RESEARCH PROTECTIONS UPDATE

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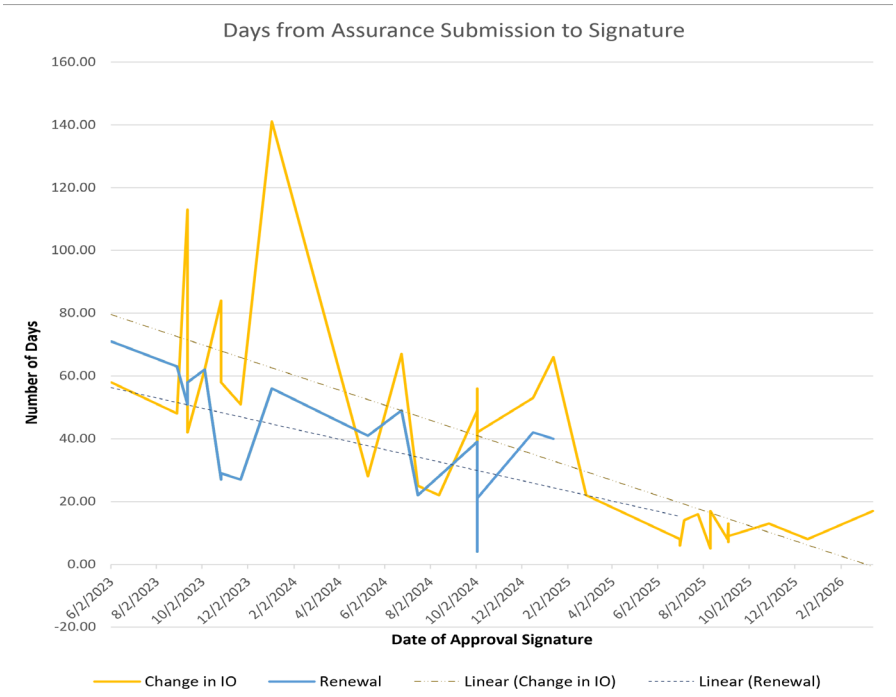
DON HRPP News

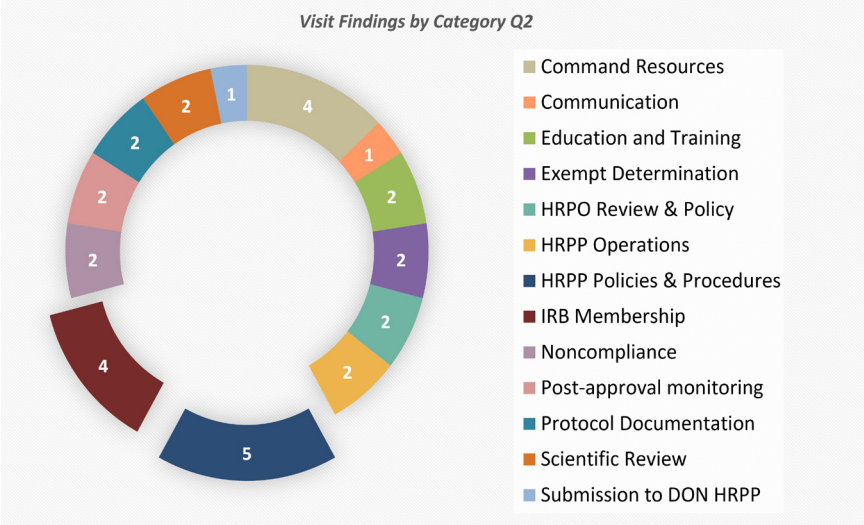
In a move to embrace the Navy's "Get Real, Get Better" (GRGB) initiative and align with Navy efforts to reduce administrative burden, the Department of the Navy Human Research Protection Program (DON HRPP) streamlined the assurance submission and approval process. In February 2025, the Navy Surgeon General delegated "By direction" signature authority for the DON assurance to the Director, DON HRPP. More than a year later, this restructuring has successfully accelerated the approval time for DON assurances. The average turnaround time for assurance renewals dropped from ~49 to ~30 days (a 38% reduction), while the processing time for changes in Institutional Official decreased from ~58 to ~12 days (a 79% reduction). Although these metrics represent a relatively brief period from which to gather conclusive data, these positive trends indicate we are on the right track.



Quarter Flashback

During courtesy visits, assist visits, and site assessments, we frequently identify required actions and recommendations designed to support our commands. Looking back at visits from 2026 Q2, the highest number of findings revolved around HRPP policies and procedures. The HRPP serves as the foundation for ethical research within DON commands, aligning these activities with both federal mandates and Department of War (DoW) regulations. Developing and maintaining standard HRPP policies and procedures is critical to ensuring scientific integrity and regulatory compliance throughout the research lifecycle.

Another primary category of concern identified during the visits was Institutional Review Board (IRB) membership. While anticipating and covering every possible scientific specialty is impossible, having a diversity of experts capable of providing oversight across a wide range of research areas is crucial. When a highly specialized protocol is encountered, the IRB should engage external consultants as needed. These independent, non-voting experts supplement the IRB by identifying complex, protocol-specific risks that extend beyond the scope of a standard ethics review. Leveraging consultants ensures rigorous scientific oversight, eliminating critical blind spots in risk assessment and strengthening the protection of human subjects.



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Current Ethics: Integrating AI Ethics into IRBs

The expanding role of artificial intelligence (AI) and machine learning (ML) in human subjects research (HSR) has introduced new considerations in how we protect participants. While IRBs are great at spotting physical risks, such as procedural complications, psychological distress, or physical safety hazards, they can encounter challenges with vulnerabilities unique to AI such as biased training data, "black box" algorithms, and how easily de-identified data can be re-identified.[1] To address these unique challenges, there is a growing push to create specialized AI Ethics Review Committees. Proponents of this reform point out that standard IRBs do not have the technical resources to track algorithmic drift or evaluate complex data privacy issues.[2,3] While the DON HRPP is currently looking into long-term solutions for this challenge, in the meantime existing boards can engage consultants, use standardized AI evaluation toolkits, or recruit data scientists to join their current roster.[4]

In the end, IRBs already have a grasp on core ethical principles like respect for persons, beneficence, and justice.[5] The priority is ensuring boards consistently apply these principles, regardless of the technology involved. Below are some prompt questions that can help an IRB when reviewing studies that involve AI or ML as either a study tool or the focus of the research.

AREA OF CONCERN	AI/ML AS AN INSTRUMENT	AI/ML AS THE FOCUS
Informed Consent[6]	Do subjects know that an AI (potentially a third-party vendor) is processing their data?	Did subjects explicitly consent to have their data used to train an algorithm for secondary/ future uses?
Data Privacy[7]	Is the data de-identified be-fore being entered into the AI tool? Is the prompt data re-tained?	Does the training dataset contain identifiable information? Can the model be used to identify subjects?
Validity & Explainability[8]	Can the researchers explain how the AI reaches its con-clusions for the specific study?	What are the testing parameters to ensure the model is accurate, relia-ble, and fair before it is deployed on human subjects?

This Month in History

This quarter, we are reflecting on two monumental longitudinal studies that both kicked off in the month of July. The first began in July 1940 at Pensacola, where the Thousand Aviator Study tracked healthy young Navy airmen over their lifetimes to analyze how the physical stresses of flight affected cardiovascular health and aging. The second began sixty-one years later in July 2001, when the Naval Health Research Center (NHRC) launched the Millennium Cohort Study to track how deployment, combat exposures, and toxic environments affect long term physical and mental health. Ultimately, while the 1940 study pioneered generational health research in the military by tracking around 1,000 pilots, the Millennium Cohort expands that legacy to a massive scale, tracking over 260,000 joint-service members to understand the enduring impacts of modern military service.

[1] National Institute of Standards and Technology, Artificial Intelligence Risk Management Framework (AI RMF 1.0), NIST AI 100-1 (Washington, DC: U.S. Department of Commerce, 2023), https://doi.org/10.6028/NIST.AI.100-1.

[2] M. Petermann et al., Looking Before We Leap: Expanding Ethical Review Processes for AI and Data Science Research (London: Ada Lovelace Institute, 2022), https://ore.exeter.ac.uk/repository/handle/10871/132324.

[3] Multi-Regional Clinical Trials Center and WCG Clinical, Framework for Review of Clinical Research Involving AI (Cambridge, MA: Harvard/MRCT Center, 2025), https://mrctcenter.org/resource/framework-for-review-of-clinical-research-involving-ai/.

[4] C. A. Makridis et al., "Informing the Ethical Review of Human Subjects Research Utilizing Artificial Intelligence," Frontiers in Computer Science 5 (2023): Article 1235226, https://doi.org/10.3389/fcomp.2023.1235226.

[5] National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (Washington, DC: U.S. Department of Health, Education, and Welfare, 1979), https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html.

[6] Multi-Regional Clinical Trials Center, Framework for Review, 18.

[7] Secretary's Advisory Committee on Human Research Protections (SACHRP), Considerations for IRB Review of Research Involving Artificial Intelligence, recommendation letter to HHS, July 25, 2022, https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-e-july-25-2022-letter/index.html.

[8] Melissa D. McCradden et al., "A Research Ethics Framework for the Clinical Translation of Healthcare Machine Learning," The American Journal of Bioethics 22, no. 5 (2022): 8–22, https://doi.org/10.1080/15265161.2021.2013977.

Have a "Good News" story or best practice you want to share? Please send your research news, success stories, tips, pictures, lessons learned, or other material related to the ethical conduct of human research to DON HRPP.

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